<u>Claims</u>:

1. A process for the manufacture of a solid dosage form which is rapidly dissolving in aqueous medium, which process comprises

(a) preparing a powder or granulate consisting of
(1) either the active substance - or part thereof - and all other ingredients of the solid dosage form; or
(2) all other ingredients of the solid dosage form except the active substance;

(b) dispensing
(1) either an auxiliary solvent or
(2) a solution or dispersion of the active substance in an auxiliary solvent,
in moulds or in the cavities of the pre-formed container intended for storage of the solid dosage form;

(c) compacting a suitable amount of the powder or granulate prepared according to (a)(1) or (a)(2) above;

(d) putting the compacted powder or granulate so obtained on the top of the liquid which according to (b)(1) or (b)(2) is in moulds or in the cavities of the pre-formed container intended for storage of the solid dosage form;

(e) removing the auxiliary solvent by applying a drying system to the units in the moulds or in the cavities of the pre-formed container intended for storage of the solid dosage form; and

(f) removing the dried units from the moulds into a suitable storage container or sealing the cavities of the pre-formed container intended for storage of the solid dosage form, respectively.

2. A process according to claim 1 for the manufacture of a solid, rapidly dissolving pharmaceutical or veterinary dosage form for oral administration, which process comprises

(a) preparing a powder or granulate consisting of
(1) either the intended dose of the active substance - or part thereof - and all other ingredients of the solid dosage form; or
(2) all other ingredients of the solid dosage form except the active substance;

(a') transferring said powder or granulate to a combined compacting/dosing system;

(a") placing moulds or a pre-formed container intended for storage of the solid pharmaceutical or veterinary dosage form within the operating range of the combined compacting/dosing system;

(b) dispensing,
(1) either an auxiliary solvent or
(2) a solution or dispersion of the active substance in an auxiliary solvent,
in moulds or in the cavities of the pre-formed container intended for storage of the solid pharmaceutical or veterinary dosage form;

(c) compacting - within the combined compacting/dosing system - a suitable amount of the powder or granulate prepared according to (a)(1) or (a)(2) above;

(d) putting the compacted powder or granulate on the top of the liquid which according to (b)(1) or (b)(2) is in moulds or in the cavities of the pre-formed container intended for storage of the solid pharmaceutical or veterinary dosage form;

(e) removing the auxiliary solvent by applying a drying system comprising one or more techniques selected from forced warm gas, microwave radiation and reduced pressure, to the units in the moulds or in the cavities of the pre-formed container intended for storage of the solid dosage form; and

(f) removing the dried units from the moulds into a suitable storage container or sealing the cavities of the pre-formed container intended for storage of the solid pharmaceutical or veterinary dosage form, respectively.

3. A process according to claim 1 for the manufacture of a solid, rapidly dissolving pharmaceutical dosage form for oral administration, which process comprises

(a) preparing a powder or granulate consisting of the active substance and all other ingredients of the solid dosage form;

(a') transferring said powder or granulate to a combined compacting/dosing system;

(a") placing a pre-formed container intended for storage of the solid pharmaceutical dosage form within the operating range of the combined compacting/dosing system;

(b) dispensing an auxiliary solvent in the cavities of the pre-formed container intended for storage of the solid pharmaceutical dosage form;

(c) compacting - within the combined compacting/dosing system - an amount of the powder or granulate prepared according to (a) above, which amount of powder or granulate contains the intended dose of the active substance;

(d) putting the compacted powder or granulate on the top of the liquid which according to (b) is in the cavities of the pre-formed container intended for storage of the solid pharmaceutical dosage form;

(e) removing the auxiliary solvent by applying a drying system comprising at least two different techniques selected from forced warm gas, microwave radiation and reduced pressure; and

(f) sealing the cavities of the pre-formed container intended for storage of the solid pharmaceutical dosage form.

4. A process according to any one of claims 1-3, where in step (b) the auxiliary solvent is selected from water, ethanol, acetone, isopropanol and any mixtures thereof.

5. A process according to any one of claims 1-4, where in step (c) the density of the compacted powder or granulate prepared is between 300 and 1000 mg/ml.

6. A process according to any one of claims 1-4, where in step (c) the density of the compacted powder or granulate is between 400 and 900 mg/ml.

7. A process according to any one of claims 1-6, where in step (c) the amount of powder or granulate which is subjected to compaction contains the intended dose of the active substance.

8. A process according to any one of claims 1-7, where in step (e) the auxiliary solvent is removed by applying simultaneously or interchangeably at least two different techniques selected from forced warm gas, microwave radiation and reduced pressure.

9. A process according to any one of claims 1-7, where in step (e) the auxiliary solvent is removed by applying simultaneously a combination of forced warm gas and microwave radiation.

10. A process according to any one of claims 1-9, wherein a solid pharmaceutical or veterinary dosage form for oral administration is manufactured.

11. A process according to claim 10, wherein a solid pharmaceutical dosage form for oral administration which is in the form of a tablet is manufactured.

12. A solid dosage form which is rapidly dissolving in aqueous medium, which dosage form comprises
(1) an active substance,
(2) a filler, and
(3) a disintegration agent,
which dosage form disintegrates when taken into the mouth within 30 seconds, and which dosage form has a density of 300-1000 mg/ml.

13. A solid pharmaceutical or veterinary solid dosage form for oral administration according to claim 12, comprising

(1) a pharmaceutically or veterinary active substance,
(2) a filler selected from the group consisting of mannitol, lactose, calcium phosphates, dibasic calcium phosphates, microcrystalline cellulose, cyclodextrine, starch, laevulose, maltitol, polydextrose, sucrose, glucose, inulin, sorbitol or xylitol, and
(3) a disintegration agent selected from the group consisting of croscarmellose Na; agents based on sodium carboxymethyl cellulose and starch, sodium glycolates of starches, poly-N-vinyl-2-pyrrolidones, starches, polymethylmethacrylates, polysaccharides or synthetic resins.

14. A solid pharmaceutical or veterinary dosage form for oral administration according to claim 12, comprising
(1) a pharmaceutically or veterinary active substance,
(2) mannitol, lactose, starch and microcrystalline cellulose, and
(3) a disintegration agent selected from the group consisting of croscarmellose Na, agents based on sodium carboxymethyl cellulose and starch, and poly-N-vinyl-2-pyrrolidones.

15. A solid pharmaceutical or veterinary solid dosage form for oral administration according to claim 12, consisting essentially of a homogeneous mixture of
(1) at least one pharmaceutically or veterinary active substance,
(2) at least one filler,
(3) at least one disintegration agent, and
(4) optionally other usual pharmaceutically or veterinarily acceptable excipients,
which dosage form disintegrates when taken into the mouth within 30 seconds, and which dosage form has a density of 400-900 mg/ml.

16. A solid pharmaceutical dosage form for oral administration according to claim 15, consisting essentially of a homogeneous mixture of
(1) at least one pharmaceutically active substance,
(2) at least one filler selected from the group consisting of mannitol, lactose, calcium phosphates, dibasic calcium phosphates, microcrystalline cellulose, cyclodextrine, starch, laevulose, maltitol, polydextrose, sucrose, glucose, inulin, sorbitol or xylitol,
(3) a disintegration agent selected from the group consisting of croscarmellose Na; agents based on sodium carboxymethyl cellulose and starch, sodium glycolates of starches, poly-

N-vinyl-2-pyrrolidones, starches, polymethylmethacrylates, polysaccharides or synthetic resins, and
(4) optionally other usual pharmaceutically acceptable excipients.

17. A solid pharmaceutical dosage form for oral administration according to claim 15, consisting essentially of a homogeneous mixture of
(1) a pharmaceutically or veterinary active substance,
(2) mannitol,
(3) a disintegration agent selected from the group consisting of croscarmellose Na, agents based on sodium carboxymethyl cellulose and starch, and poly-N-vinyl-2-pyrrolidones; and
(4) optionally other usual pharmaceutically excipients.

18. A solid pharmaceutical dosage form for oral administration according to any one of claims 12-17, wherein the active substance is selected from the group consisting of (a) diclofenac, ketoprofen, ibuprofen, aspirin, paracetamol, melatonin and pharmaceutically acceptable salts thereof, and (b) pharmaceutically acceptable salts of calcium, magnesium and zinc.

19. A solid pharmaceutical or veterinary dosage form for oral administration according to any one of claims 12-18, wherein the composition contains as other usual excipients (4) a lubricant and optionally other usual excipients.

20. A solid pharmaceutical or veterinary dosage form for oral administration according to claim 19, wherein the lubricant is talc.

21. A solid pharmaceutical or veterinary dosage form for oral administration according to any one of claims 12-20, wherein the composition contains as other usual excipients (4) a lubricant, one or more sweeteners and optionally other usual excipients.

22. A solid pharmaceutical or veterinary dosage form for oral administration according to any one of claims 12-21, wherein the filler (2) is present in an amount of at least 30 weight-%, and the disintegrating agent (3) is present in an amount of from 0.5 up to 15 weight-% of the total dosage form.

23. A solid pharmaceutical or veterinary dosage form for oral administration according to any one of claims 12-22, which dosage form is manufactured without applying any compression force to the mixture of the components (1), (2), (3) and optionally (4) during the last step of manufacture concerning the solid dosage form, i.e. process step (e).

24. A solid pharmaceutical or veterinary dosage form for oral administration according to any one of claims 12-23, which dosage form is manufactured without applying any freeze-drying process.

25. A solid pharmaceutical or veterinary dosage form for oral administration according to any one of claims 12-24, which dosage form is manufactured by starting with the preparation of a homogeneous mixture of all the components (1), (2), (3) and optionally (4) of the dosage form.

26. A solid dosage form according to any one of claims 12-25, which is intended for the pharmaceutical field.